



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 4, 2015

Volcano Corporation
Mary Stanners
Regulatory Affairs Specialist
3721 Valley Centre Drive, Suite 500
San Diego CA 92130

Re: K150442

Trade/Device Name: Volcano Visions PV .018 Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: May 22, 2015
Received: May 26, 2015

Dear Mary Stanners:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over a large, light gray, semi-transparent watermark of the FDA logo.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150442

Device Name

Visions® PV.018 Digital IVUS Catheter

Indications for Use (Describe)

The Visions® PV .018 Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The Visions® PV .018 Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

SPONSOR: Volcano Corporation
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130

CONTACT/SUBMITTER: Mary Stanners
Regulatory Affairs Specialist
Volcano Corporation
3721 Valley Centre Drive
San Diego, California 92130
Tel: (858) 764-1296

DATE OF SUBMISSION: August 31, 2015

DEVICE: Volcano Visions® PV .018 Digital IVUS Catheter

Trade Name: Volcano Visions® PV .018 Digital IVUS Catheter

Common Name: Diagnostic Intravascular Catheter

Classification and Product Codes:

CFR Number	Class	Product Code
21 CFR 870.1200 Diagnostic Intravascular Catheter	II	OBJ
21 CFR 892.1570 Diagnostic Ultrasound Transducer	II	ITX

PANEL: Cardiovascular

PREDICATE DEVICE: Visions F/X Model 82700 (K944004)

DEVICE DESCRIPTION:

The Visions® PV .018 Digital IVUS Catheter incorporates a cylindrical ultrasound transducer array located near the distal tip of the catheter. The array radiates acoustic energy into the

surrounding tissue and detects the subsequent ultrasonic echoes. The information from the echoes is used to generate real-time images of the coronary or peripheral vessels.

The Visions® PV .018 catheter utilizes an internal lumen that allows the catheters to track over a 0.018" (0.46 mm) guide wire. The guide wire exits from the guide wire lumen approximately 31 cm proximal to the catheter tip. The PV .018 catheters are introduced either percutaneously or via surgical cut down into the vascular system.

The Visions® PV .018 catheter may only be used with Volcano imaging systems, such as the Volcano s5™, Volcano s5i™, Volcano CORE Mobile, and Volcano CORE imaging systems. The catheter will not operate if connected to any other imaging system.

INDICATIONS FOR USE:

The **Visions® PV .018 Digital IVUS Catheter** is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The **Visions® PV .018 Digital IVUS Catheter** is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The modifications made to the Visions® PV .018 Digital IVUS Catheter (changes in catheter material, catheter scanner assembly and catheter connector assembly) do not affect the intended use of the device or technologies included as part of the device and they do not alter the fundamental scientific technologies. The indications for use are identical to those of the currently marketed predicate device (Visions F/X Model 82700; cleared under K944004). The modified catheter is substantially equivalently to currently marketed predicate device.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the modified device. Bench testing was conducted against product specification and evaluated the following:

- Shelf Life
- Floppy Tip Tensile Testing
- ESL Tensile Testing
- Signal Processing

All bench testing was successfully completed and met the pre-determined acceptance criteria. The successful completion of performance testing concluded that the modified Visions® PV .018 catheter is substantially equivalent to the currently marketed Visions F/X (Model 82700) catheter.

Biocompatibility testing was conducted on the device and the following tests were successfully completed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity
- Pyrogenicity
- ASTM Hemolysis
- Partial Thromboplastin Time
- *In vivo* Thromboresistance
- C3a Complement Activation
- SC5-b Complement Activation
- Bacterial Endotoxins (LAL)
- LEAP Latex Elisa for Antigenic Protein
- Platelet and Leukocyte Counts
- Chemical Characterization

The successful completion of performance testing and biocompatibility testing concluded that the modified Visions® PV .018 catheter is substantially equivalent to the currently marketed Visions F/X (Model 82700) catheter.